

WHAT IS CLAIMED IS:

1. A system for predicting blood glucose values in a patient, comprising:
  - a remote wireless non-invasive spectral device configured for generating a spectral scan of a body part of the patient;
  - a remote invasive device configured for generating a constituent value for the patient; and
  - a central processing device configured for predicting a blood glucose value for the patient based upon the spectral scan and the constituent value.
2. The system as recited in claim 1 wherein the central processing device is further configured for receiving at least one of the constituent value and information regarding the spectral scan over an at least partially wireless path.
3. The system as recited in claim 1 wherein the central processing device is further configured for receiving at least one of the constituent value and information regarding the spectral scan by a mode of data transmission.
4. The system as recited in claim 3 wherein the mode of data transmission is at least one of a cellular data link, a telephone modem, a direct satellite link, an Internet link, and an RS232 data connection.
5. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device is configured for transmitting information regarding the spectral scan by a mode of data transmission.
6. The system as recited in claim 5 wherein the mode of data transmission is at least one of a cellular data link, a telephone modem, a direct satellite link, an Internet link, and an RS232 data connection.

7. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device includes a wireless spectrometer.
8. The system as recited in claim 7 wherein the wireless spectrometer includes an infrared spectrometer.
9. The system as recited in claim 7 wherein the wireless spectrometer comprises a light source for irradiating the body part and at least one detector for detecting radiation reflected off or transmitted through the body part.
10. The system as recited in claim 9 wherein the at least one detector is on a side of the body part proximate to the light source for detecting light reflected off the body part.
11. The system as recited in claim 9 wherein the at least one detector is on a side of the body part remote from the light source for detecting light transmitted through the body part.
12. The system as recited in claim 9 wherein the light source emits radiation in multiple wavelengths, the system further comprising a filter for restricting passage of light through the filter in only a specific predetermined range of wavelengths.
13. The system as recited in claim 12 wherein the filter is situated between the light source and the body part, such that the filtering means allows passage of light in only a specific predetermined range of wavelengths to pass to the body part.
14. The system as recited in claim 12 wherein the filter is situated between the body part and the at least one detector, such that the filter allows passage of only a specific predetermined range of wavelengths reflected off or transmitted through the body part to pass to the at least one

detector.

15. The system as recited in claim 12 wherein the filter is at least one linear variable filter.

16. The system as recited in claim 15 further comprising a solid state translation device operatively connected to the at least one linear variable filter and configured for moving the at least one linear variable filter.

17. The system as recited in claim 16 wherein the at least one detector comprises a plurality of individual detectors.

18. The system as recited in claim 16 wherein the solid state translation device is a piezoelectric bimorph.

19. The system as recited in claim 18 further comprising a lever device coupling the piezoelectric bimorph to the at least one linear variable filter and configured for amplifying a movement of the at least one linear variable filter relative to a movement of the piezoelectric bimorph.

20. The system as recited in claim 12 wherein the at least one detector is at least one array detector.

21. The system as recited in claim 12 wherein the at least one detector is at least one diode.

22. The system as recited in claim 12 wherein the filter is a bandpass filter.

23. The system as recited in claim 22 wherein the filter includes a plurality of bandpass filters.

24. The system as recited in claim 12 wherein the filter is a grating.
25. The system as recited in claim 24 wherein the grating is a diffraction grating.
26. The system as recited in claim 9 wherein the light source emits light in only a specific predetermined range of wavelengths, and wherein the at least one detector detects light reflected off or transmitted through the body part in the specific predetermined range of wavelengths.
27. The system as recited in claim 9 wherein the light source emits light in multiple wavelengths, and wherein each of the at least one detector detects light reflected off or transmitted through the body part in only a specific predetermined range of wavelengths.
28. The system as recited in claim 7 wherein the wireless spectrometer sends information regarding the spectroscopic data to the central processing device through infrared radiation or near infrared radiation.
29. The system as recited in claim 9 wherein the light source is capable of illuminating a plurality of positions in a region of the body part.
30. The system as recited in claim 29 wherein the light source includes a fiber optic bundle for illuminating the plurality of positions.
31. The system as recited in claim 30 wherein the light source includes a plurality of near-infrared light emitting diodes, each for illuminating a respective position of the plurality of positions.
32. The system as recited in claim 30 wherein the at least one detector is disposed in the

region for detecting light reflected off or transmitted through the body part.

33. The system as recited in claim 32 wherein each of the at least one detector is configured for detecting a respective wavelength of light.

34. The system as recited in claim 30 further comprising:

a plurality of optical fibers spaced apart on the region for receiving radiation reflected off or transmitted through the body part and delivering the respective radiation to the at least one detector; and

a switching device coupled to each of the plurality of optical fibers and to the at least one detector, the switching device configured to connect one of the respective optical fiber at a time to the at least one detector.

35. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device includes a transmitter configured for wirelessly transmitting information regarding the spectral scan.

36. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device is handheld.

37. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device includes a sensor, a monitor and a handheld processing device.

38. The system as recited in claim 1 further comprising a remote processing device configured for communicating with the central processing device .

39. The system as recited in claim 38 wherein the remote processing device is further configured for transmitting information regarding the spectral scan to the central processing

device.

40. The system as recited in claim 38 wherein the remote wireless non-invasive spectral device is configured for transmitting information regarding the spectral scan to the remote processing device.

41. The system as recited in claim 38 wherein the remote processing device is further configured for transmitting information regarding the spectral scan to at least one of a doctor's office and a hospital.

42. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device includes a wireless spectrometer, the wireless spectrometer including:

a light source;

a focusing optical device configured for focusing light from the light source onto the body part;

a linear variable filter device disposed so as to receive light transmitted through or reflected by the body part and pass light in at least one predetermined narrow wavelength band; and

an array detector device configured for receiving and detecting light from the linear variable filter device.

43. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device includes a wireless spectrometer, the wireless spectrometer including:

a light source configured for emitting light onto the body part, the light source including a prism light guide; and

at least a first and a second detector disposed adjacent the light source, the at least first and second detector being configured for receiving light reflected from the body part.

44. The system as recited in claim 43 wherein the prism light guide is an  $\text{SiO}_2$  rectangular

prism light guide.

45. The system as recited in claim 43 wherein the prism light guide is an  $\text{SiO}_2$  triangular prism light guide and wherein the at least first and second detector include a third detector, the first, second and third detector being disposed adjacent respective sides of the triangular prism light guide.

46. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device includes a wireless spectrometer, the wireless spectrometer including:

    a light source configured for emitting light onto the body part;

    a linear variable filter device configured to pass light in at least one predetermined wavelength band and disposed so as to receive light transmitted through or reflected from the body part;

    an array detector device configured for receiving the light passed by the linear variable filter device;

    a detector imaging optic device configured for directing the light passed by the linear variable filter device onto the array detector device;

    an enclosure configured for receiving the linear variable filter device, the detector imaging optic device and the array detector device; and

    a transparent element disposed at a wall of the enclosure and configured for passing the light transmitted through or reflected by the body part to the linear variable filter.

47. The system as recited in claim 46 wherein the linear variable filter device includes a plurality of multi-range filters, each of the multirange filters passing a respective predetermined wavelength band.

48. The system as recited in claim 46 further comprising at least one drive device for moving the linear variable filter device so as to change the at least one predetermined wavelength band.

49. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device is portable and further comprising a storage media device configured for storing at least one of information regarding the spectral scan and an equation for interpreting the spectral scan.

50. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device is portable and configured for transmitting information regarding the spectral scan to the central processing device.

51. The system as recited in claim 1 further comprising a remote processing device configured for communicating with the central processing device and wherein the remote wireless non-invasive spectral device is portable and configured for transmitting information regarding the spectral scan to at least one of the central processing device and the remote processing device.

52. The system as recited in claim 1 wherein the remote invasive device is configured for taking a blood sample by a venipuncture, a fingerstick, and a heelstick so as to perform the generating.

53. The system as recited in claim 1 wherein the remote invasive device is configured for transferring the constituent value to the remote wireless non-invasive spectral device.

54. The system as recited in claim 1 wherein the remote invasive device is configured for transmitting at least one of the constituent value and information regarding the spectral scan by a mode of data transmission.

55. The system as recited in claim 1 wherein the central processing device is further configured for receiving the spectral scan from the remote wireless non-invasive spectral device and for storing a modeling equation for predicting blood glucose values in the patient, the central

processing device being further configured for regenerating the modeling equation based upon a plurality of spectral scans of the patient from the remote wireless non-invasive spectral device and a corresponding plurality of constituent values for the patient from the remote invasive device, and for predicting a blood glucose value for the patient based upon a subsequent non-invasive spectral scan of the patient with the remote wireless non-invasive spectral device and the regenerated modeling equation.

56. The system as recited in claim 1 wherein the central processing device is further configured for transmitting information to at least one of the patient, a doctor's office and a hospital.

57. The system as recited in claim 1 wherein the central processing device includes a computer.

58. The system as recited in claim 1 further comprising a base module configured for receiving information regarding the spectral scan wirelessly from the remote wireless non-invasive spectral device and for communicating with the central processing device, and wherein the central processing device includes a file server and a data base device linked to the file server through a scheduler/sender device.

59. The system as recited in claim 1 wherein the remote wireless non-invasive spectral device is disposed at a home of the patient.

60. The system as recited in claim 1 wherein:

the remote wireless non-invasive spectral device is further configured for transmitting the spectral scan to the central processing device and for generating a plurality of second spectral scans of the body part;

the remote invasive device is further configured for generating a plurality of second

constituent values for the patient respectively associated with the plurality of second spectral scans; and

the central processing device is further configured for:

dividing the plurality of second spectral scans and constituent values into a calibration subset and a validation subset;

transforming the second spectral scans in the calibration sub-set and the validation subset by applying a plurality of a first mathematical function to the calibration sub-set and the validation sub-set to obtain a plurality of transformed validation data sub-sets and a plurality of transformed calibration sub-sets;

resolving each transformed calibration data sub-set by at least one of a second mathematical function to generate a plurality of modeling equations;

selecting a best modeling equation of the plurality of modeling equations;

storing the best modeling equation in a central computer;

predicting the patient's blood glucose level using the best modeling equation; and

regenerating the best modeling equation if the spectral scan falls outside a range for the modeling equation.

61. The system as recited in claim 60 wherein the best modeling equation is selected as a function of calculating a figure of merit (FOM), the FOM being defined as:

$$FOM = \sqrt{(SEE^2 + 2 * SEP^2) / 3}$$

where:

SEE is the Standard Error of Estimate from the calculations on the calibration data;

SEP is the Standard Error of Estimate from the calculations on the validation data; and the modeling equation which provides the best correlation between the spectral data in the validation sub-set and the corresponding constituent values in the validation sub-set being identified as the modeling equation with the lowest FOM value.

62. The system as recited in claim 60 wherein the at least one second mathematical function includes one or more of a partial least squares, a principal component regression, a neural network, and a multiple linear regression analysis.

63. The system as recited in claim 60 wherein the first set of mathematical functions include performing a normalization of the spectral scan, performing a first derivative on the spectral scan, performing a second derivative on the spectral scan, performing a multiplicative scatter correction on the spectral scan, performing smoothing transform on the spectral scan, a Savitsky-Golay first derivative, a Savitsky-Golay second derivative, a mean-centering, a Kubelka-Munk transform, and a conversion from reflectance/transmittance to absorbence.

64. The system as recited in claim 60 wherein the first set of mathematical functions are applied singularly and two-at-a-time.

65. The system as recited in claim 60 wherein the remote wireless non-invasive spectral device is further configured for transmitting the spectral scan to the central processing device over an at least partially wireless transmission path.

66. A system for predicting blood glucose values in a patient, comprising:  
a remote wireless non-invasive spectral device configured for generating a spectral scan of a body part the patient;  
a remote invasive device configured for generating a constituent value for the patient; and  
a central processing device configured for receiving the spectral scan from the remote wireless non-invasive spectral device and for storing a modeling equation for predicting blood glucose values in the patient, the central processing device predicting a blood glucose value for the patient based upon the spectral scan and the modeling equation, the central processing device regenerating the modeling equation based upon a plurality of spectral scans of the patient from the remote wireless non-invasive spectral device and a corresponding plurality of constituent

values for the patient from the remote invasive device, and predicting a blood glucose value for the patient based upon a subsequent non-invasive spectral scan of the patient with the remote wireless non-invasive spectral device and the regenerated modeling equation.

67. A method for predicting blood glucose values in a patient, comprising:
  - generating a spectral scan of a body part the patient using a remote wireless non-invasive spectral device;
  - generating a constituent value for the patient using a remote invasive device; and
  - predicting a blood glucose value for the patient using a central processing device based upon the spectral scan and the constituent value.
68. The method as recited in claim 67 further comprising:
  - receiving the spectral scan from the remote wireless non-invasive spectral device;
  - storing a modeling equation for predicting blood glucose values in the patient using the central processing device;
  - regenerating the modeling equation using the central processing device based upon a plurality of spectral scans of the patient from the remote wireless non-invasive spectral device and a corresponding plurality of constituent values for the patient from the remote invasive device; and
  - predicting a blood glucose value for the patient based upon a subsequent non-invasive spectral scan of the patient with the remote wireless non-invasive spectral device and the regenerated modeling equation.
69. The method as recited in claim 67 wherein the remote spectral device includes an infrared spectrometer.
70. The method as recited in claim 67 wherein the infrared spectrometer includes a grating spectrometer, a diode array spectrometer, a filter-type spectrometer, an Acousto Optical Tunable

Filter spectrometer, a scanning spectrometer, an ATR spectrometer, and a nondispersive spectrometer.

71. The method as recited in claim 67 wherein the remote wireless non-invasive spectral device communicates with the central processing device by a mode of data transmission.

72. The method as recited in claim 67 wherein the spectral device controls administering an amount of a drug to the patient.

73. The method as recited in claim 67 wherein the central processing device includes a workstation capable of holding a plurality of spectral scans and modeling equations for a plurality of patients.

74. An automated method for predicting blood glucose values using a noninvasive spectroscopic technique, comprising the steps of:

- (a) taking a plurality of measurements of a patient's blood glucose levels using a noninvasive spectral device and an invasive glucose monitoring method;
- (b) associating a constituent value measured by the invasive glucose monitoring method with the blood glucose level measured by the spectral device;
- (c) dividing the plurality of spectral scans and constituent values into a calibration subset and a validation subset;
- (d) transforming the spectral scans in the calibration sub-set and the validation subset by applying a plurality of a first mathematical function to the calibration sub-set and the validation sub-set to obtain a plurality of transformed validation data sub-sets and a plurality of transformed calibration sub-sets;
- (e) resolving each transformed calibration data sub-set in step (d) by at least one of a second mathematical function to generate a plurality of modeling equations; and
- (f) selecting a best modeling equation of the plurality of modeling equations;

- (g) storing the best modeling equation in a central computer;
- (h) acquiring a spectral scan from the patient using a remote wireless noninvasive spectral device;
- (i) transmitting the spectral scan from step (h) to the central computer of step (g);
- (j) predicting the patient's blood glucose level using the best modeling equation; and
- (k) regenerating the best modeling equation if the spectral scan falls outside a range for the modeling equation.

75. The method as recited in claim 74 wherein the best modeling equation is selected as a function of calculating a figure of merit (FOM), the FOM being defined as:

$$FOM = \sqrt{(SEE^2 + 2 * SEP^2) / 3}$$

where:

SEE is the Standard Error of Estimate from the calculations on the calibration data;

SEP is the Standard Error of Estimate from the calculations on the validation data; and the modeling equation which provides the best correlation between the spectral data in the validation sub-set and the corresponding constituent values in the validation sub-set being identified as the modeling equation with the lowest FOM value.

76. The method as recited in claim 74 wherein the at least one second mathematical function includes one or more of a partial least squares, a principal component regression, a neural network, and a multiple linear regression analysis.

77. The method as recited in claim 74 wherein the first set of mathematical functions include performing a normalization of the spectral scan, performing a first derivative on the spectral scan, performing a second derivative on the spectral scan, performing a multiplicative scatter correction on the spectral scan, performing smoothing transform on the spectral scan, a Savitsky-

Golay first derivative, a Savitsky-Golay second derivative, a mean-centering, a Kubelka-Munk transform, and a conversion from reflectance/transmittance to absorbence.

78. The method as recited in claim 74 wherein the first set of mathematical functions are applied singularly and two-at-a-time.

79. The method as recited in claim 74 wherein the transmitting of step (i) takes place over an at least partially wireless transmission path.